DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 23, 2014

JMS North America Corporation
Sho Hosoki
Regulatory
22320 Foothill Blvd., Suite 350
Hayward, CA 94541

Re: K142564
Trade/Device Name: JMS SysLoc® MINI A.V. Fistula Needle Set (V4)
JMS SysLoc® MINI Apheresis Needle Set (V4)
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: FIE
Dated: November 20, 2014
Received: December 1, 2014

Dear Sho Hosoki,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 04: Indications for Use

510(K) Number (if known): K142564

Device Name: JMS SysLoc® MINI A.V.Fistula Needle Set (V4)
JMS SysLoc® MINI Apheresis Needle Set (V4)

Indications for Use: Use for temporary cannulation non-implantable, less than 30 days) to vascular access for extra corporeal blood treatment. The device is intended for single use only and has an anti-stick feature integrated as part of the Needle Set which aids in prevention of needle-stick injuries

Prescription Use ____✓___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 05: 510(k) Summary [807.92(c)]

Owner [807.92(a)1]:

Company Name: JMS North America Corp.
Company Address: 22320 Foothill Blvd., Suite 350
Hayward, CA 94541

Telephone: 510-888-9090
Fax: 510-888-9099

Contact Person: Sho Hosoki
Summary Preparation Date: 08/01/2014

Device of Submission [807.92(a)(2)]

Classification Name: Needle, Fistula
Intravascular Catheter
Proprietary Name: JMS SysLoc® MINI A.V. Fistula Needle Set
JMS SysLoc® MINI Apheresis Needle Set
Classification: Class II
Product Code: FIE, FOZ
Code of Federal Regulations: 21 CFR 876.5540

Note: Same trade name is to be used for both modified and predicate device, thus for clearer differentiation, the modified device will be denoted as SysLoc® MINI (V4) and the predicate device as SysLoc® MINI (V3).

Predicate Device [807.92(a)(3)]

K Number	Product	Company
K110157	JMS SysLoc® MINI A.V. Fistula Needle Set & JMS SysLoc® MINI Apheresis Needle Set (V3)	JMS North America Corporation

Device Description [807.92(a)(4)]

SysLoc® MINI (V4) is intended as non-implanted blood access device, which consists of flexible tube and needle with integrated sharp safety features as described in 21 CFR 876.5540. SysLoc® MINI (V4) comes with a rotational feature and the needle is retracted with the wing sheath after deliberate release of secured external lock, and final locking is assured by an audible 'click' sound when the hub/tube is pulled rearwards.

Intended Use [807.92(a)(5)]

SysLoc® MINI (V4) is intended for temporary cannulation (non-implantable, less than 30 days) to vascular access for extracorporeal blood treatment. The device is intended for single use only and has an anti-stick feature integrated as part of the Needle Set which aids in prevention of needle-stick injuries.

Section 05: 510(k) Summary [807.92(c)]

Predicate Comparison [807.92(a)(6)] & [807.92(b)(1)]

	Modified Device	Predicate
Device Name	SysLoc® MINI (V4).	SysLoc® MINI (V3).
510(k) #	---	K110157
Classification	Class II	Class II
Intended Use	Remains the same as (V3).	SysLoc® MINI (V3) is intended for temporary cannulation (non-implantable, less than 30 days) to vascular access for extracorporeal blood treatment. The device is intended for single use only and has an anti-stick feature integrated as part of the Needle Set which aids in prevention of needle-stick injuries.
Technical Characteristic of Anti-stick	Remains the same as (V3).	Retract needle into SysLoc® MINI (V3) Wing Sheath after releasing external lock. Needle slides into the sheath and locks in position to prevent needle stick
Physical Specification	Remains the same as (V3) except: Reduction in filter paper of PE pouch	SysLoc® MINI (V3) (with safety feature) is integrated into the wing design. There is no pre-attached component to the device that may interfere the dialysis session.
Material	See Section 15 for material comparison	
Labeling	See Section 13 for Labeling	
Biocompatiblity	See Section 15 for biocompatibility	
Sterilization	ETO sterilization	ETO sterilization
Performance Specification	Remains the same as (V3)	SysLoc® MINI (V3) device required very minimum force when retraction and needle is locked after use. SysLoc® MINI (V3) sheath will not be punctured by needle when properly used. SysLoc® MINI (V3) device is able to be operated by one hand and two-handed techniques.

Conclusion [807.92(b)(3)]

SysLoc® MINI (V4) has the same intended usage as the predicate device SysLoc® MINI (V3) K110157. Bench testing was conducted to verify that the SysLoc® MINI (V4) device is performing as intended to be a safe and effective medical device. Evaluation data and reports are enclosed within this submission document. The information provided in this submission clearly demonstrates the substantial equivalence of SysLoc® MINI (V4) to the predicate device JMS SysLoc® MINI A.V. Fistula Needle Set (V3) & JMS SysLoc® MINI Apheresis Needle Set (V3) K110157.